K120242

PATHWAY MEDICAL TECHNOLOGIES

FEB 24 2012

510(k) SUMMARY

General Information:

Date of Summary Preparation:	January 26, 2012
Name and Address of Manufacturer:	Pathway Medical Technologies, Inc. 10801 120th Ave NE Kirkland, Washington 98033
Contact Person:	Brit Baird Regulatory Affairs Manager Phone: 425-636-4137 Fax: 425-636-4001
Device Trade Names:	JETSTREAM Navitus™ L System
Common Name:	Peripheral Atherectomy Catheter
Regulation Number:	21 CFR 870.4875
Regulation Name:	Intraluminal Artery Stripper
Regulatory Class:	Class II
Classification Panel:	Cardiovascular
Product Code:	MCW

Performance Standards: Performance Standards do not currently exist for these devices. None are established under Section 514.

Device Description: The Jetstream Navitus L System is an atherectomy catheter system designed with an expandable cutting tip intended for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through a port in the Catheter tip to an external collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

The Jetstream Navitus L System consists of two primary components: a Catheter with Control Pod and a Console, which are packaged separately. Each of these system components is described generally as follows:

- **Jetstream Navitus L Catheter with Control Pod:** A sterile, single-use unit consisting of an electrically-driven Catheter with attached Control Pod. As with the predicate device, the Jetstream Navitus L Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities, and the Control Pod provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a double pouched tray.

- **PV Console:** A reusable compact PV Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The PV Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

This 510(k) is for modifications to the Jetstream Navitus System. The primary modifications of this 510(k) are to increase the cutting tip and expandable blade diameters (i.e., from 2.1 to 2.4 mm for the cutting tip, and from 3.0 to 3.4 mm for the expandable blades), and decrease the overall catheter length (from 135 to 120 cm).

Indications for Use: The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Substantially Equivalent Devices: Pathway Medical cites the Jetstream Navitus™ System (K110626) as the primary predicate device for the aforementioned modifications and substantial equivalence basis. However, the design rationale for and device testing of the modified device also includes references to the additional predicate Pathway Medical devices listed in the table below:

Predicate Devices	Pathway Medical Predicate 510(k)
Jetstream G3® SF 1.6 System	K111229
Jetstream G3® SF System	K101334
Jetstream G3® System	K101221 K093456 K092332
Jetstream G3® L System	K100462 K093918
Jetstream G2® NXT System	K091509
Jetstream Pathway PV™ Atherectomy System	K082186
Pathway PV™ Atherectomy System	K081328

Testing Summary: To demonstrate substantial equivalence of the modified Jetstream Navitus System to the predicate Jetstream Navitus System, the technological and performance characteristics were evaluated using *in vitro* testing for the primary (and supporting) modifications, as outlined below:

- Dimensional Verification
- Heat Generation
- System Reliability/Life Test
- Aspiration Efficiency & Crossing Time
- Speed Drop – Flexibility
- Material Liberation (Teflon & Polyimide)
- Rotational Speed
- Accessory Compatibility
- Infusion & Aspiration Flow Rates
- Catheter Pull
- Catheter Trackability and Pushability
- Torque to Failure
- Contrast Injection
- Aorta Strip Test
- Layered Dissection Model

The results from these tests:

- demonstrate that the technological and performance characteristics of the modified Jetstream Navitus System are comparable to the predicate Jetstream Navitus System,

- support the safety and effectiveness of the modifications that are the subject of this 510(k), and
- ensure the modified device can perform in a manner equivalent to the predicate Jetstream Navitus System with the identical intended use.

Conclusion (Statement of Equivalence): The data and information presented within this submission (including *in vitro* testing) and the similarities between the modified and predicate devices support a determination of substantial equivalence, and therefore market clearance of the modified Jetstream Navitus System through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2012

Pathway Medical Technologies, Inc.
c/o Mr. Brit Baird
Regulatory Affairs Manager
10801 120th Ave NE
Kirkland, WA 98033

Re: K120242
Trade/Device Name: Jetstream Navitus L Systems
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: January 26, 2012
Received: January 27, 2012

Dear Mr. Baird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K120242

Device Name: JETSTREAM Navitus™ L System

Indications for Use: The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120242